Date: 27-May-2021

FSN Ref: REF-EN 01698

Urgent Field Safety Notice

Name of Product: INTERCEPT Blood System for Plasma, Processing Set for Plasma

Product Code(s): INT3103B, INT3104B, INT3105B, INT3130B

FSN Type: New

Type of Action: Mislabelling in the Instructions for Use and product labels

Affected Lots: All lots distributed since June 2019

Details of affected device and description of the problem:

The INTERCEPT Blood System for plasma is intended for the ex vivo preparation and storage of pathogen inactivated plasma intended for transfusion. The set is used to inactivate bacteria, viruses, parasites and leukocytes in plasma to reduce the risk of transfusion-transmitted infection.

In 2015, Cerus and the contract manufacturer of the INTERCEPT Plasma processing set jointly initiated a project to remove DEHP-containing components from the processing set. After completion of the project, product labels and Instructions for Use (IFU) were updated to remove the DEHP symbol or text and residual risk statement. In April 2021, it was discovered that two of the components, breakaway cannulae and Y-junction connectors, do contain DEHP.

Plasma component exposure to DEHP is limited by the amount of time (approximately <15 minutes) required to transfer plasma through the processing set during the INTERCEPT pathogen inactivation process. Plasma storage containers in which treated plasma remains until the time of transfusion to a patient do not contain DEHP. The risk to patient safety of receiving INTERCEPT plasma prepared using this processing set is negligible due to the transient contact that plasma has with the DEHP containing components during INTERCEPT processing. Patients do not have direct contact with INTERCEPT processing sets. DEHP levels in blood components after use of the processing set are estimated to be well below those resulting from other medical applications containing PVC components. The negligible risks associated with DEHP released to the plasma component must be weighed against the benefits of therapeutic transfusion and inactivation of harmful viruses, bacteria and other pathogens.

Correction of the product: Cerus is initiating a correction to the product labels and Instructions for Use. Cerus also plans to validate non-DEHP containing breakaway cannulae and Y-junction connectors to replace these components. This planned change will result in removal of all DEHP containing materials from the INTERCEPT Blood System for Plasma.

Advice on action to be taken by the user:

Carefully read this Urgent Field Safety Notice. Please complete and return the attached Customer Reply Form.

The local Competent Authority has been informed of this notice.

Cerus is committed to providing quality products and services. Please be assured that all customer reports and product quality issues are taken very seriously in an effort to make sure our products are safe and reliable. Please feel free to contact me, your Sales Representative, or Cerus Customer Services if further information is needed or if you have specific questions about this notice or our products.

Respectfully,

Carol M Moore
Senior Vice President, Quality Assurance and Regulatory Affairs
Cerus Corporation
cmoore@cerus.com
Phone: 925-288-6361

Attachment: Customer Reply Form